REMARKS

Prior to the present amendment, claims 1-5 were pending. By this amendment, applicants have canceled claims 1-5, and added new claims 6-11. Accordingly, claims 6-11 are currently pending.

This present amendment is submitted in response to the Office Communication dated August 12, 2004. The Office Communication states that applicants' amendment dated May 10, 2004 in response to the Office Action of February 10, 2004 does not comply with 37 CFR §1.145.

According to the Office Communication, the amendment of May 10, 2004 "presented claims directed to inventions distinct from and independent of the invention previously claimed." Thus, the examiner required applicant to restrict the claims to the invention previously claimed.

Accordingly, applicants have complied with the request of the examiner. The present amendment presents claims to the invention which was previously claimed. Specifically, new claims 6-11 are directed to a method for detecting IgA or IgG anti-transglutaminase antibodies. Applicants also address below the rejections raised in the Office Action dated February 10, 2004.

In the Office Action dated February 10, 2004, claims 1-5 were rejected under 35 U.S.C. §112, first paragraph for alleged lack of enablement. The examiner contends that the method does not appear to work as claimed. According to the examiner, it is unclear how the binding sites on the transglutaminase IgA or IgG are prevented from being saturated with the labeled antigen. The examiner asserts that if the binding sites are saturated, they would not be available to bind to the unlabeled, immobilized antigen. Therefore, according to the examiner, no label would be detected, leading to a false negative result.

The examiner further states that the specification recites an example where the assay is conducted. However, the examiner states that it cannot be determined whether the example is theoretical or the assay was actually conducted.

Applicants respectfully disagree with the examiner. Applicants would like to point out to the examiner that a limit of detection is inherent in any type of assay. In fact, such a low amount of antibody in the sample may not be statistically significant. What is important is the amount that is significant. Therefore, the claimed invention is enabled.

To support applicants' position that the claimed invention is enabled, applicants would like to bring to the examiner's attention the Sorell et al. article published on March 16, 2002 (after the priority date of the claimed invention) in the journal, *Lancet* (volume 359, pages 945-946). Both inventors of the claimed invention are listed as authors of the Sorell et al. article. For the examiner's convenience, a copy of the Sorell et al. article is enclosed as exhibit 1.

In Sorell et al., the claimed assay was used to determine the presence of IgA or IgG antibodies to transglutaminase in fifty untreated celiac patient and forty non-celiac patients. All fifty patients with celiac disease tested positive with the claimed immunochromatographic system. A positive result indicates the presence of antibodies to transglutaminase. Further, all forty non-celiac patients tested negative with the claimed immunochromatographic system. See the paragraph bridging page 945 and 946 of Sorell et al.

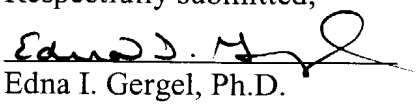
Thus, the data presented in Sorell et al. supports applicants' position that the claimed invention is enabled. Further, the experiment reported in Sorell et al. is similar to the example recited in the specification. Accordingly, applicants respectfully request that the rejection under §112 allegedly for lack of enablement be withdrawn.

Claims 1-5 were rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite for various reasons. Applicants have canceled claims 1-5, and have added new claims

6-11. In view of applicants' amendments to the claims and the above argument that the claimed invention is enabled, applicants respectfully request that the §112 rejection be reconsidered and withdrawn.

In view of the above amendments and remarks, allowance of pending claims 6-11 is earnestly requested. If the examiner has any questions regarding this amendment, the examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,



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